In the Supreme Court of the United States

OCTOBER TERM, 1969

No. 1436

CARTER-WALLACE, INC., PETITIONER

v.

ROBERT H. FINCH, SECRETARY OF HEALTH, EDUCATION, AND WELFARE AND CHARLES EDWARDS, COMMISSIONER OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 417 F. 2d 1086.

JURISDICTION

The judgment of the court of appeals was entered on November 25, 1969. On February 10, 1970, the Chief Justice extended the time for filing a petition

for a writ of certiorari to April 21, 1970, and on April 17 the petition was filed. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the evidence supports the ruling of the Commissioner of Food and Drugs that meprobamate is a depressant drug subject to control under the Federal Food, Drug and Cosmetic Act as amended by the Drug Abuse Control Amendments of 1965.

2. Whether the ruling as to meprobamate was properly made applicable to combination drugs containing meprobamate.

STATUTES INVOLVED

The pertinent statutes, 21 U.S.C. (Supp. IV) 321(v)(3), and 21 U.S.C. (Supp. IV) 360a(f)(2)(B)(ii), are set forth at pp. 70a and 73a of the petition.

STATEMENT

In July 1965, Congress amended the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*, to apply specific controls upon the manufacture, sale and distribution of "depressant or stimulant drugs." P.L. 89-74, 79 Stat. 226. This term was broadly defined to include—

> (3) any drug which contains any quantity of a substance which the Secretary [of Health, Education, and Welfare], after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its de-

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pressant or stimulant effect on the central nervous system * * * [21 U.S.C. 321(v)(3)].

Pursuant to the authority set forth in the Drug Abuse Control Amendments of 1965, and delegated to the Commissioner of Food and Drugs (21 C.F.R. (1966 ed.) 2.90), on January 18, 1966, the Commissioner proposed the listing of meprobamate as a drug having a potential for abuse because of its depressant effect upon the central nervous system. The proposal sought to designate all drugs containing any amount of meprobamate (and 16 other drugs) as subject to the controls authorized by the 1965 Amendments. Interested persons were invited to submit their views in writing.

On March 19, 1966, the Commissioner issued an order designating meprobamate and all drugs containing meprobamate as subject to control under the Amendments (31 F.R. 4679). Petitioner, a pharmaceutical firm engaged through a subsidiary in the manufacture, sale and distribution of meprobamate under the brand name Miltown, and of certain drugs containing meprobamate as an ingredient, filed objections to the Commissioner's order. Following a hearing,[1] conducted intermittently from June 27 to September 16, 1966, the FDA Hearing Examiner, in a report dated January 13, 1967, found substantial evidence that meprobamate has a potential for abuse because of its depressant effect on the central nervous

[1] The 4,891-page transcript of the hearing has not been filed with the Clerk of this Court. Excerpts from it appear in Carter-Wallace's Appendix and Respondents' Appendix in the court of appeals, which are included in the record filed with this Court. In all, 62 witnesses, including 50 medical doctors, testified, and 142 exhibits were introduced in evidence. See Pet. App. 35a-36a.

system (Pet. App. 20a-34a). The examiner further found that, although the record did not include substantial evidence that petitioner's drug compounds containing meprobamate have a potential for abuse, the controls authorized by the pertinent statute, *supra*, also apply to the combination drugs (Pet. App. 33a-34a).

After additional oral argument, the Commissioner, on December 6, 1967, issued his "Findings of Fact and Conclusions of Law," dated November 28, 1967 (Pet. App. 35a-65a). Among the facts found therein by the Commissioner to have been established by "substantial evidence of record" were that meprobamate presents a health hazard when consumed excessively; that persons have consumed the drug in sufficient amounts to cause chronic intoxication; that chronic ingestion has also caused personality changes and has led to the commission of crimes, neglect of children, and deterioration of domestic relationships; that individuals who have a propensity to become addicted to a drug, and especially alcoholics, have taken meprobamate to satisfy their craving; that the drug has been used as a means of committing suicide; that substantial amounts of meprobamate have been unlawfully distributed either through regular channels (doctors and pharmacies) or in the black market; that individuals have used devious methods to obtain the drug from lawful distributors; that prolonged ingestion causes the body to build a tolerance, so that increased quantities are needed for the desired effect; that sudden withdrawal after chronic ingestion is characterized by certain symptoms, the severity of which depends upon the degree of dependency on the drug; and

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that individuals who are addicted to certain other drugs and alcohol will turn to meprobamate if their supply of their primary drug is cut off. Accordingly, the Commissioner concluded (Pet. App. 64a-65a):

> 5. Meprobamate is a drug which because of its depressant effect on the central nervous system has a substantial potential for significant abuse within the meaning of the amendments (21 U.S.C. 321(v)(3)).
>
> 6. Meprobamate is a "depressant or stimulant drug" as defined in the amendments * * *, and is therefore subject to control under the amendments (21 U.S.C. 360a). Any drug which contains any quantity of meprobamate is a "depressant or stimulant drug" as defined in the amendments * * * and is also subject to control under the amendments * * *.

In the court of appeals petitioner acknowledged that meprobamate has a potential for abuse, but argued that the evidence failed to support the Commissioner's finding that the potential for abuse is connected to meprobamate's depressant effect on the central nervous system. In addition, petitioner alleged that its drugs containing meprobamate combined with others should not have been included in the order because of a lack of evidence that they have a substantial potential for significant abuse. Finally, petitioner charged bias on the part of the hearing examiner, as demonstrated particularly by his evidentiary rulings. The court of appeals rejected these contentions and affirmed the Commissioner's order (Pet. App. 1a-19a).

ARGUMENT

1. In this Court petitioner does not assail the fairness of the hearing examiner, but renews his attack

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upon the soundness of the Commissioner's findings relative to the depressant effect of meprobamate upon the central nervous system and the inclusion of the combination drugs in his control order. In petitioner's view, when the opinions of government witnesses are balanced against the conflicting opinions furnished by its witnesses, the standard of "substantial evidence" required to sustain the Commissioner's ruling has not been met.

The opinion of the court of appeals discusses this claim at length. The court recognized that the precise reason why meprobamate affects users as it does cannot be fully explained in the current state of scientific knowledge, so that expert opinions differ on how the drug operates. The experts agree, however, that the drug acts upon individuals very similarly to barbiturates and alcohol, which are known to have depressant effects upon the central nervous system. For example, excessive use of meprobamate can cause physical dependence, euphoria, and withdrawal symptoms similar to those caused by barbiturates and alcohol. And, as with these other depressants, the body reacts to continued consumption of meprobamate by building a tolerance, so that an increased dosage becomes necessary to produce the desired effect. Finally, there is evidence that meprobamate suppresses symptoms of withdrawal from alcohol and barbiturates; in other words, a cross-tolerance can be developed between meprobamate and other depressants. Drug-prone alcoholics, of which there are a substantial number in the United States, are likely to abuse meprobamate if given easy access to it. With these facts established by the record, there is indeed substantial

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evidence to support the findings of the Commissioner and his consequent conclusion, affirmed by the court of appeals, that meprobamate has a depressant effect on the central nervous system, and therefore has a potential for significant abuse within the meaning of the Drug Abuse Control Amendments of 1965.

This is not a case where, as petitioner contends, the court of appeals failed to review the entire record, or where the evidence given credence does not amount to "substantial evidence" (Pet. 13). As petitioner itself notes, the court of appeals opinion refers to the conflict between the testimony of witnesses for Carter-Wallace and that of government witnesses. At most, the situation presented was one where the fact-finder was called upon to resolve conflicts of expert opinion. His resolution of the conflicts against petitioner provides no occasion for review since the evidence relied upon was credible and the inferences drawn were reasonable. *Santa Fe Drilling Co.* v. *National Labor Relations Board*, 416 F. 2d 725, 730 (C.A. 9); *Erickson* v. *Federal Trade Commission*, 272 F. 2d 318 (C.A. 7), certiorari denied, 362 U.S. 940.

2. Since the determination that meprobamate was a drug subject to control under 21 U.S.C. 321(v)(3) was proper, the Commissioner's order necessarily applied to drug combinations which include meprobamate as an ingredient. This is so because the pertinent statutory definition, *supra*, embraces the primary drug and "any drug which contains any quantity" of the drug found to have a potential for abuse. Petitioner is not, however, precluded from securing an exception to the application of the Commissioner's or-

der, if one is desired and warranted. This can be done by instituting proceedings for an exemption under 21 U.S.C. 360a(f)(2), and establishing affirmatively that the amount of meprobamate contained in the combination drugs is not sufficient to regard them as having a potential for abuse because of their depressant effect on the central nervous system. Contrary to petitioner's contention, the hearing examiner's statement that there was a "lack of substantial evidence" in the record of the abuse potential of the combination drugs (Pet. 15; Pet. App. 33a) is not a substitute for an affirmative finding that the combination drugs qualify for exemption. The hearings to date obviously were not directed toward the combination products, and detailed evidence was not introduced on this question because a determination of abuse potential as to meprobamate itself was necessary before any issue regarding the combinations arose.

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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